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EXAMINER				
GROSS, CHRISTOPHER M				
ART UNIT		PAPER NUMBER		
1639				
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01/02/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/642,776

**Applicant(s)**

ROY ET AL.

**Examiner**

CHRISTOPHER M. GROSS

**Art Unit**

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 19-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 37, 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

Responsive to communications entered 10/14/2008. Claims 1-38 are pending. Claims 19-36 are withdrawn. Claims 1-18,37-38 are examined herein.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/14/2008 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

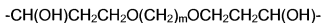
### ***Election/Restrictions***

Applicant's election with traverse of group II, drawn to a protein-substrate complex (claims 10-18) is again acknowledged.

Applicant's election without traverse of "silica surface" for the species of support of claim 5 in the reply filed on 1/25/2008 is again acknowledged.

Applicant's election without traverse of "succinyl group" for the species of specificity-determining ligand of claim 2 in the reply filed on 1/25/2008 is again acknowledged.

Applicant's election with traverse of:



for the species of spacer of claim 4 is again acknowledged.

Group I, drawn to a specificity determining substrate (claims 1-9) and group II were rejoined in the interest of compact prosecution in the office action mailed 10/11/2006.

With regard to new claims 37 and 38, it is noted the response filed 10/14/2008 does *not* include a listing of all claims readable on the elected species, including any claims subsequently added, as required by MPEP § 809.02(a).

Furthermore, in accordance with current office policy said response does not include an identification of the current claims encompassing the elected invention, including claims added after the election.

Applicant is required in response to this and any future office actions to provide a listing of which of the active claims read on the elected species and elected invention.

### ***Priority***

This application was filed 1/13/2005 and claims benefit of provisional application 60/403,747 filed 08/16/2002.

### ***Withdrawn Rejection(s)***

The rejection of claims 6 and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 1-3,5-6,10-12,14-15 under 35 U.S.C. 102(b) as being anticipated by **Keyes** (US Patent 4,714,676) is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 1-6,8-9,10-15,17-18 under 35 U.S.C. 102(b) as being anticipated by **Comb et al** (US Patent 5,843,247) is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 1-18 under 35 U.S.C. 103(a) as being unpatentable over **Comb et al** (US Patent 5834247) **in view of Margel** (US Patent 4732811) is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 1-18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement concerning new matter is hereby withdrawn in view of applicant's amendments to the claims.

### ***New Claim Rejection - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7,10-16,37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by **Krupey** (US Patent 5534597 – IDS entry 1/5/2007).

The claimed subject matter per claim 1 is drawn to a specificity-determining substrate

wherein the specificity-determining substrate consists of a specificity-determining ligand bound to a support, wherein the specificity-determining substrate forms a complex in a homogenous fashion with a protein comprised in a proteomic sample, wherein the protein is elutable from the complex, and provided that the substrate is other than a crosslinked chitosan bearing a diethylamino or diethylaminoethyl ligand

Claims 2-7,10-16,37-38 represent variations thereof.

**Krupey** teaches, throughout the document and especially the abstract and title, water insoluble cross-linked polyhydroxy polycarboxylic acid (CPPA) compositions for adsorbing proteins thereto.

The limitation "wherein the specificity-determining substrate forms a complex in a homogenous fashion with a protein comprised in a proteomic sample, wherein the protein is elutable from the complex," set forth in claim 1 is taken as intended use and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets claims 1-7. Here, said CPPA compositions, such as composition VI of Krupey consist of a succinyl group as a specificity-determining ligand and is not chitosan bearing a diethylamino or diethylaminoethyl ligand, therein reading on claim 1.

Said CPPA hydrogels containing succinyl specificity ligands of Krupey read on:  $\text{HOOC}(\text{CH}_2)_2\text{CO}-$  (elected species) of claim 2 and  $\text{R1-COOH}$  of claim 3 when R1 is an aliphatic carboxyl.

Krupey et al teach diaminohydroxyalkyl spacers in formula II, reading on claim 4.

Said CPPA hydrogels reads on claims 5 and 14 and is not a surface, reading on claims 6 and 15.

With regard to claims 10-16, comprising a protein molecule in complex with the specificity-determining substrate it is noted the same CPPA hydrogels of Krupey are used in examples 1-7 of the present application. And in this vein, Krupey teaches elution of bound proteins column 3, lines 43-44, reading on proteins being elutable, as set forth in claims 10-13. Krupey teaches in example 3 human gamma globulins, a proteomic sample of plural proteins, further reading on claims 10-13 as well as claims 37-38.

Krupey teaches a 5% w/v polymer suspension in column 9, line 62, reading on claims 7 and 16.

### ***New Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18,37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Krupey** (US Patent 5534597 – IDS entry 1/5/2007) as evidenced by Lihme et al (US Patent 6919436)

**Krupey** is relied on as above.

Krupey does not teach: chromatography matrices of silica, polysaccharide or chitosan (claims 5,8,9,14,17,18).

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to incorporate specificity ligands such as the succinyl groups of Krupey into a silica (elected species), polysaccharide or chitosan chromatography matrices.

One of ordinary skill in the art would have been motivated to incorporate specificity ligands such as the succinyl groups of Krupey into a silica (elected species), polysaccharide or chitosan chromatography matrix because each represents an art recognized equivalent for the same purpose, a basis for obviousness according to MPEP 2144.06 and recently codified in KSR Int'l Co. v. Teleflex Inc No. 04-1350 (S.Ct. Apr 30, 2007) /550 U.S.\_\_\_\_\_, 82 USPQ2d 1995 (2007), where The Supreme Court stated "when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result."



Here, evidence provided by Lihme et al in the paragraph bridging columns 10-11 indicate materials such as agarose (a polysaccharide), chitosan and silica all represent art recognized chromatography matrices.

One of ordinary skill in the art would have had a reasonable expectation of success in incorporating specificity ligands such as the succinyl specificity groups of Krupey into a silica (elected species), polysaccharide or chitosan chromatography matrix because such materials have been successfully used for chromatography for quite some time.

In conclusion, the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, *prima facie* obvious.

***New Claim Rejection(s) – 35 USC § 112***

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18,37-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection concerns "new matter."

Claims 1,10-13 and 37-38 each recite the limitation a "proteomic sample."

Applicant has attempted to point to support for said limitation on p 1 in the field of the

invention; p 3, 2nd paragraph; p 11, 5<sup>th</sup> paragraph; p 17, 1<sup>st</sup> paragraph; and the examples.

However, the examiner fails to find support for proteomic samples in the recited passages, as follows. Pages 1,3 and 17 each concern the *discipline* of proteomics and do not recite samples. Page 11 recites a glyco-proteomic system, again with no mention of samples. The examiner does not find support for proteomic samples in the examples.

New claims 37 and 38 recite a "plurality of proteins." Said proteins are elutable, in reference to claim 1, from which claims 37 and 38 ultimately depend.

Applicant has attempted to point to support for a plurality of proteins on p 4 paragraph 4 and p 13 paragraph 2 and the claims as originally filed .

However, the examiner fails to find support for a plurality of proteins being elutable in the recited passages as follows. Page 13 paragraph 2 recites "As used herein including the claims, the article "**a**", when used to describe an item or object, refers both to the singular and plural forms of the item or object. As an example the phrase "a protein" may designate either one protein or a plurality of proteins," whereas p 4 paragraph 4 recites "separating the fluid so contacted from the complex; thereby resolving the **first** protein from the fluid." Emphasis added. Because the passage on p 4, refers uses the article "first" as opposed "a," as defined on p 13, the combination does not provide support for a plurality of proteins being elutable as set forth in new claims 37 and 38. The examiner does not find support in the claims as originally filed.

Accordingly, the specification as originally filed provided no implicit or explicit support for "proteomic samples," or a plurality of proteins being elutable.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER M. GROSS whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross  
Examiner  
Art Unit 1639

cg

/ Christopher S. F. Low /  
Supervisory Patent Examiner, Art Unit 1639